

DIVISION 121

OREGON PRESCRIPTION DRUG PROGRAM

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431-121-2000

Definitions

(1) “340B” means Section 340B of the Public Health Service Act, “Limitation on Prices of Drugs Purchased by Covered Entities,” and any and all related rules, guidance, interpretations, and operational directives adopted by the federal Health Resources and Services Administration (HRSA) or any other governmental agency with jurisdiction over the enforcement of Section 340B.

(2) “Administrator” means the Administrator of the Oregon Prescription Drug Program (OPDP).

(3) “Authority” means the Oregon Health Authority.

(4) “Critical Access Pharmacy (CAP)” means a pharmacy in Oregon that is further than a ten-mile radius from any other pharmacy. If one CAP’s ten-mile radius intersects with that of another CAP, both shall be considered a CAP if either CAP’s closure could result in impaired access for rural areas.

(5) “Designated Entity” means an entity contracted by the Authority to perform administrative duties of the OPDP including but not limited to determining program prices, processing and paying claims, issuing identification cards, maintaining eligibility files, network development maintenance, and performing replenishment administration. Designated entities may include but are not limited to pharmacy benefits managers, third party administrators, insurance carriers, health maintenance organizations (HMOs), mail order and specialty drug suppliers, replenishment administrators, group purchasing organizations, and wholesalers.

(6) “Discount Card Program” or “DCP” means a state pharmacy benefit program for eligible uninsured individuals pursuant to ORS 414.312(4)(e) administered by the OPDP.

(7) “Group Purchasing Organization (GPO)” means any organization purchasing on a group basis established to meet the criteria of the Nonprofit Institutions Act, 15 USC 13c, or that is exempt under the Robinson Patman Antidiscrimination Act, 15 USC 13, or is a governmental entity performing traditional government functions.

(8) “Mail Order Pharmacy” means a pharmacy that fulfills prescriptions by mail or other delivery service.

(9) “Member” means individuals enrolled in a participating program to receive services under the OPDP.

(10) “Participating Program” means:

(a) A group, facility, or entity that is eligible to participate in the OPDP pursuant to ORS 414.312(4) and has a participation agreement with the OPDP; or

(b) A DCP for individual Oregon residents who lack or are underinsured for prescription drug coverage pursuant to ORS 414.312(4)(e).

(11) “Pharmacy Benefit Manager (PBM)” means an entity that negotiates and executes contracts with pharmacies, manages Preferred Drug Lists (PDL), negotiates rebates with prescription drug manufacturers, and serves as an intermediary between the Administrator, prescription drug manufacturers, and pharmacies.

(12) “Pharmacy Provider” means retail, mail order, and specialty drug outlets that participate in the OPDP and that contract with the Authority or a designated entity as a pharmacy provider.

(13) “Preferred Drug List (PDL)” means a list of preferred prescription drugs in selected classes that the Authority, in consultation with the Office for Oregon Health Policy and Research (OHPR), has determined represent the most effective drugs available at the best possible price.

(14) “Prescription Drug” means:

(a) A drug prescribed by a prescribing practitioner;

(b) Supplies necessary to administer a prescription drug in a safe and effective manner, including but not limited to inhaler, spacers, diabetic test strips, syringes, and meters.

(15) “Prescribing Practitioner” means a physician or other practitioner authorized by law to prescribe prescription drugs.

(16) “Prescription Drug Claims Processor” (PDCP) means an entity that processes and pays prescription drug claims, adjudicates pharmacy claims, transmits prescription drug prices and claims data between pharmacies and the OPDP, and processes payments to pharmacies.

(17) “Program Price” means the reimbursement rates and prescription drug prices established by the OPDP Administrator directly or indirectly through a contract with a designated entity, including program cost, dispensing or administration fees, and all applicable manufacturers discounts and rebates.

(18) “Rebate” means all payments or discounts whether retrospective or not, including promotional or volume-related refunds, incentives or other credits however characterized, pre-arranged with pharmaceutical companies on certain prescription drugs, which are paid to or on behalf of OPDP or a designated entity, and are directly attributable to the utilization of certain drugs by members including administrative fees and software or data fees paid by pharmaceutical companies to OPDP or a designated entity. Rebate includes all rebates, discounts, payments or benefits (however characterized) generated by participating program’s claims, or derived from any other payment or benefit for the dispensing of prescription drugs or classes or brands of drugs within participating program or arising out of any relationships OPDP or designated entity has with pharmaceutical companies, including but not limited to rebate sharing, market share allowances, educational allowances, gifts, promotions, or other form of revenue.

(19) “Replenishment Administration” means tracking GPO or 340B program usage by pharmacy providers and ordering replacement inventory including associated reporting; GPO and 340B retail and mail order pharmacy contracting; GPO and 340B contracting; or as otherwise defined by contract.

(20) “Retail Pharmacy” means a pharmacy in a retail store and excludes any mail order pharmacy or specialty pharmacy.

(21) “Specialty Pharmacy” means a pharmacy provider where specialty drugs are dispensed and delivered to members or to prescribing practitioners for members.

(22) “Third Party Administrator (TPA)” means an entity that, in addition to being a PDCP, facilitates program management including processing and paying prescription drug claims; transmitting prescription drug prices and claims and enrollment data between pharmacies and the OPDP and its participating programs; maintaining enrollment and issuing identification cards; and processing payments to pharmacies. The TPA may be contracted through the Authority or PBMs, or other designated entities.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

Hist.: OHP 1-2004, f. & cert. ef. 9-24-04; OHP 2-2006(Temp), f. & cert. ef. 11-28-06 thru 5-23-07; OHP 2-2007(Temp), f. & cert. ef. 5-16-07 thru 11-6-07; OHP 3-2007, f. & cert. ef. 8-3-07; OHP 3-2009, f. & cert. ef. 10-1-09; Renumbered from 409-030-0000 by DMAP 1-2011, f. 2-10-11, cert. ef. 3-1-11; DMAP 10-2012, f. 3-6-12, cert. ef. 3-13-12; Renumbered from 410-121-2000, OPDP 1-2015, f. & cert. ef. 2-18-15

431-121-2005

General Administration

(1) The Administrator, or designee, may:

(a) Negotiate price discounts and rebates on prescription drugs with prescription drug manufacturers and GPOs;

(b) Purchase prescription drugs on behalf of participating programs;

(c) Contract with a PDCP or PBM to adjudicate pharmacy claims and transmit program prices to pharmacies;

(d) Determine program prices and reimburse or replenish pharmacies for prescription drugs dispensed or transferred;

(e) Adopt and implement a PDL for the OPDP;

(f) Develop a system for allocating and distributing the operational costs of the program and any rebates obtained to participating programs; and

(g) Cooperate with any state or regional consortia in bulk purchasing of prescription drugs.

(2) The Administrator or designated entity shall oversee the implementation of the OPDP, including review of member eligibility information, participating program information, and pharmacy provider compliance with program requirements. The Administrator, or designated entity, shall review records or other information, including health information, necessary to perform oversight responsibilities.

(3) The Administrator shall establish processes, terms, and conditions describing how the entities identified in ORS 414.312(4) may participate in the OPDP as a participating program, including entities otherwise subject to ORS 731.036(6).

(4) The Administrator or designated entity may contract with a PBM and directly or indirectly with pharmacy providers as the Administrator or designated entity considers necessary to maintain statewide access for OPDP members including consideration for CAP providers.

(5) The Administrator or designated entity may contract with replenishment administrators, GPO's, 340B providers, and pharmacy providers as necessary to utilize discount purchasing programs.

(6) Annually, no later than November 1, the Office of Rural Health shall determine any Oregon pharmacies that meet CAP status and report them to the OPDP for CAP designation. OPDP shall send the current list of all Oregon retail pharmacies to the Office of Rural Health no later than October 1 each year.

(7) Pursuant to ORS 414.312(5), the state agency that receives federal Medicaid funds and is responsible for implementing the state's medical assistance program may not participate in the program. The phrase "state agency" for this purpose means the Authority, which is the state Medicaid agency that administers funds from Title XIX of the Social Security Act, and is responsible for implementing the state's Medicaid program. State agency does not include other programs or functions within the Authority that do not receive federal Medicaid funds, such as the Public Employees' Benefit Board and the Oregon Educators Benefit Board.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

Hist.: OHP 1-2004, f. & cert. ef. 9-24-04; OHP 2-2006(Temp), f. & cert. ef. 11-28-06 thru 5-23-07; Administrative Correction, 6-16-07; OHP 3-2007, f. & cert. ef. 8-3-07; OHP 3-2009, f. & cert. ef. 10-1-09; Renumbered from 409-030-0005 by DMAP 1-2011, f. 2-10-11, cert. ef. 3-1-11; DMAP 10-2012, f. 3-6-12, cert. ef. 3-13-12; Renumbered from 410-121-2005, OPDP 1-2015, f. & cert. ef. 2-18-15

431-121-2010

Pharmacy Providers

(1) The pharmacy shall contract with the Authority, or its designated entity, and must be licensed with their state Board of Pharmacy to be a pharmacy provider for the OPDP.

(2) The pharmacy provider must sign a pharmacy provider contract and comply with all applicable state and federal laws, regulations, rules, and the terms and conditions of the contract. The contract authorizes the pharmacy provider to serve members in the OPDP and outlines program compliance requirements.

(3) A contract may be issued to a qualified pharmacy provider upon:

(a) Completion and signature of the contract by the pharmacy provider or a person authorized by the pharmacy provider to bind the organization;

(b) Verification of Pharmacy licensing with their State Board of Pharmacy; and

(c) Approval of the contract by the Authority or its designated entity.

(4) To contract for the OPDP, the pharmacy provider must:

(a) Accept the program price in effect on the date of the transaction as established by the Administrator or designated entity including but not limited to dispensing fees which may be charged to the member;

(b) Maintain sufficient documentation of transactions to resolve disagreements with the member or participating program about the amount charged for the prescription drugs;

(c) Reimburse the member or participating program directly for overcharges as determined by program price in effect on the date of the transaction;

(d) Provide access to records and data required by the designated entity to administer claims, reimbursement, and other tasks as necessary for OPDP claims processing; and

(e) Not charge members for costs incurred by the pharmacy provider for the electronic transmittal of the program price from the Authority to the pharmacy.

(5) Pharmacy providers may advertise participation in the OPDP, provided that:

(a) Advertising or marketing materials must be accurate and not misleading or confusing to members or the public about participation in the OPDP or the savings offered by the pharmacy provider.

(b) The pharmacy provider must cease all advertisements pertaining to participation in the program if the Authority suspends or terminates the contract.

(6) The Administrator or designated entity shall, at its discretion, suspend or remove a pharmacy provider from the OPDP if the pharmacy provider loses licensure or fails to comply with applicable state and federal laws, rules, and regulations, and the terms and conditions of the contract.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

Hist.: OHP 1-2004, f. & cert. ef. 9-24-04; OHP 2-2007(Temp), f. & cert. ef. 5-16-07 thru 11-6-07; OHP 3-2007, f. & cert. ef. 8-3-07; OHP 3-2009, f. & cert. ef. 10-1-09; Renumbered from 409-030-0010 by DMAP 1-2011, f. 2-10-11, cert. ef. 3-1-11; DMAP 10-2012, f. 3-6-12, cert. ef. 3-13-12; Renumbered from 410-121-2010, OPDP 1-2015, f. & cert. ef. 2-18-15

431-121-2020

Program Price

(1) The price for a prescription drug a pharmacy provider may charge a member under the OPDP is the lesser of the following on the date of the transaction:

(a) The program price, or

(b) The pharmacy provider's usual and customary price, including program cost and dispensing fee.

(2) The designated entity shall transmit the price of the prescription drugs to the pharmacy providers electronically.

(3) The OPDP is limited to prescription drugs prescribed in the name of and for the use by the member, except as otherwise provided in section (7) of this rule.

(4) Prescription drug benefit access shall be available on member identification cards.

(5) The OPDP does not include prescriptions for over-the-counter drugs.

(6) The Administrator, or designated entity, may establish different program prices for CAP providers in rural areas to maintain statewide access to the OPDP.

(7) Unique pricing arrangements may be agreed upon between pharmacy providers and designated entity to accommodate group purchasing or 340B pricing for qualified entities.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

Hist.: OHP 1-2004, f. & cert. ef. 9-24-04; OHP 2-2006(Temp), f. & cert. ef. 11-28-06 thru 5-23-07; OHP 2-2007(Temp), f. & cert. ef. 5-16-07 thru 11-6-07; OHP 3-2007, f. & cert. ef. 8-3-07; OHP 3-2009, f. & cert. ef. 10-1-09; Renumbered from 409-030-0020 by DMAP 1-2011, f. 2-10-11, cert. ef. 3-1-11; DMAP 10-2012, f. 3-6-12, cert. ef. 3-13-12; Renumbered from 410-121-2020, OPDP 1-2015, f. & cert. ef. 2-18-15

431-121-2030

Preferred Drug List

(1) The Administrator shall consider any PDL developed and recommended by OHPR that identifies preferred choices of prescription drugs within therapeutic classes for particular diseases and conditions, including generic alternatives, for use in the OPDP by participating programs.

(2) The OPDP shall develop a PDL that participating programs may choose to adopt for beneficiaries of their prescription drug benefit program. The PDL shall include the most effective prescription drugs at the lowest possible prices, taking into account negotiated price discounts and rebates available to the OPDP, while allocating and distributing the operational costs of the OPDP.

(3) If a participating program uses the PDL developed by the OPDP, it must be used in conjunction with that participating program's benefit plan including all pharmacy management programs the participating program has or adopts.

(4) OPDP shall make the PDL available to individuals enrolled in the OPDP.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

Hist.: OHP 1-2004, f. & cert. ef. 9-24-04; OHP 3-2009, f. & cert. ef. 10-1-09; Renumbered from 409-030-0030 by DMAP 1-2011, f. 2-10-11, cert. ef. 3-1-11; DMAP 10-2012, f. 3-6-12, cert. ef. 3-13-12; Renumbered from 410-121-2030, OPDP 1-2015, f. & cert. ef. 2-18-15

431-121-2050

Enrollment

(1) Participating programs, other than the DCP, shall enroll for participation through the designated entity chosen by the OPDP to administer the participating program's enrollment and claims processing.

(a) Eligibility for members of a participating program shall be maintained electronically between the participating program and designated entity.

(b) Participating programs or designated entities shall issue identification cards to members at initial enrollment and renewal, and between those times as needed.

(2) Residents of Oregon who do not have prescription drug coverage or who are underinsured for prescription drug coverage may be individually enrolled by the designated entity.

(a) The designated entity shall issue identification cards to members.

(b) Individuals who are eligible for Medicare Part D prescription drug coverage may participate in the program.

(3) The OPDP may charge a nominal fee to participate in the program.

Stat. Auth.: ORS 414.320

Stats. Implemented: ORS 414.312 - 414.320

Hist.: OHP 1-2004, f. & cert. ef. 9-24-04; OHP 2-2006(Temp), f. & cert. ef. 11-28-06 thru 5-23-07; OHP 2-2007(Temp), f. & cert. ef. 5-16-07 thru 11-6-07; OHP 3-2007, f. & cert. ef. 8-3-07; OHP 3-2009, f. & cert. ef. 10-1-09; Renumbered from 409-030-0050 by DMAP 1-2011, f. 2-10-11, cert. ef. 3-1-11; DMAP 10-2012, f. 3-6-12, cert. ef. 3-13-12; Renumbered from 410-121-2050, OPDP 1-2015, f. & cert. ef. 2-18-15

431-121-2065

Contracted Services

(1) The Administrator may procure goods and services to perform any of the functions of OPDP.

(2) The Administrator shall delegate procurement authority to the Authority's designated Procurement Officer for OPDP goods and services, except as the Administrator determines to retain such authority in a particular case and as otherwise provided in section (4) of this rule.

(3) The Administrator shall act as the Authority's representative for each contract. The Administrator may delegate in writing the representative's responsibilities to a designee. The agency's representative may participate with the Authority's designated Procurement Officer in all aspects of procurement.

(4) OPDP's mechanism for and administration of the enrollment of participating groups shall not constitute procurements subject to this rule.

Stat. Auth.: ORS 414.312

Stats. Implemented: ORS 414.312, 414.314, 414.316 & 414.318

Hist.: OHP 3-2007, f. & cert. ef. 8-3-07; OHP 3-2009, f. & cert. ef. 10-1-09;

OHP 2-2010(Temp) f. 4-20-10, cert. ef. 4-21-10 thru 10-17-10; OHP 6-2010, f.

9-23-10, cert. ef. 10-1-10; Renumbered from 409-030-0065 by DMAP 1-2011,

f. 2-10-11, cert. ef. 3-1-11; DMAP 10-2012, f. 3-6-12, cert. ef. 3-13-12; Renum-

bered from 410-121-2065, OPDP 1-2015, f. & cert. ef. 2-18-15